

**IN THE UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA**

MAUREEN PIEKANSKI

Plaintiff,

v.

ALEX AZAR II, in his official capacity
as the Secretary of the Department of
Health and Human Services.

Defendant.

Case No. 3:20-cv-00687-RDM

(Hon. Robert D. Mariani)

Electronically Filed

PLAINTIFF'S STATEMENT OF UNDISPUTED MATERIAL FACTS

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I. INTRODUCTION

Pursuant to Federal Rule of Civil Procedure 56 and Middle District of Pennsylvania LR 56.1, Plaintiff Maureen Piekanski (“Plaintiff”) hereby submits the following Statement of Undisputed Material Facts in support of her Motion for Summary Judgment.

II. STATEMENT OF UNDISPUTED MATERIAL FACTS

1. Plaintiff is Maureen Piekanski, a Medicare Part B beneficiary. (*See Exhibit A*¹ (“Gulin Decision”), at A.R.² 2465.)

2. Ms. Piekanski was diagnosed with glioblastoma multiforme (GBM) in 2011. (Gulin Decision, at A.R. 2466.)

3. Two articles published in the Journal of the American Medical Association (JAMA) in 2015 and 2017 resulted from a clinical trial on TTFT, showing that TTFT increased the 2-year survival rate of GBM patients by more than 38% and nearly tripled the five-year survival rate. (**Exhibit J**, at A.R. 3432-3441; **Exhibit K**, at A.R. 3421-3431.)

4. She has repeatedly litigated the issue of whether her tumor treating field therapy (“TTFT”) is medically reasonable and necessary to treat her

¹ Unless otherwise noted, all exhibits referenced herein correspond to the exhibits with the same designation that have been attached to the Declaration of Mark W. Fidanza, Esq. filed contemporaneously herewith.

² Wherever possible, pin cites will direct the Court to the page numbers assigned to the Administrative Record (“A.R.”) in this matter.

glioblastoma multiforme (“GBM”), a malignant brain tumor. She received four Administrative Law Judge determinations finding that her TTFT device is a covered benefit and medically reasonable and necessary to treat her GBM. (*See generally* **Exhibits A, D-F.**)

5. Mrs. Piekanski was represented by attorney Bridget Noonan at the Judge Jeffrey Gulin hearing held on October 17, 2018. (Gulin Decision, at A.R. 2465.)

6. On November 7, 2018, prior to the ALJ’s decision underlying the immediate case, Judge Gulin issued a favorable decision for ALJ Appeal No. 1-7835229465. (Gulin Decision, at A.R. 2461-2470.)

7. ALJ Gulin’s November 7, 2018 decision covers Mrs. Piekanski’s claims for TTFT coverage for the months of September – November 2017. (Gulin Decision, at A.R. 2465.)

8. In this case, ALJ Gulin noted that “Mrs. Piekanski seeks coverage for Elec Stim Cancer Treatment...”). (Gulin Decision, at A.R. 2465.)

9. Mrs. Piekanski raised the issue of Medicare coverage for her TTFT device by appealing the Qualified Independent Contractor’s negative reconsideration decision in this case. (Gulin Decision, at A.R. 2465.)

10. At issue in ALJ Gulin’s decision was whether TTFT was a Medicare covered benefit for Mrs. Piekanski (“Whether the Elec Stim Cancer Treatment

(E0766) provided to the Beneficiary...meet Medicare coverage criteria.”) (sic). (Gulin Decision, at A.R. 2466.)

11. Judge Gulin found that TTFT was a covered Medicare benefit for Mrs. Piekanski (“The Appellant is entitled to Medicare coverage for the Elec Stim Cancer Treatment (E0766) provided on the dates of service...”). (Gulin Decision, at A.R. 2470.)

12. At issue in Judge Gulin’s case was whether TTFT was “medically reasonable and necessary” for Mrs. Piekanski (“[w]hether the services provided are medically necessary...”). (Gulin Decision, at A.R. 2466.)

13. ALJ Gulin found that “the service is medically reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act” for Mrs. Piekanski. (Gulin Decision, at A.R. 2470.)

14. The Secretary did not appeal this decision. (Fidanza Declaration ¶ 5.)

15. Mrs. Piekanski was represented by attorney Bridget Noonan at the Judge Ryan Glaze hearing held on January 3, 2019. (See **Exhibit C** (“Glaze Unfavorable Decision”), at A.R. 2594.)

16. Judge Ryan Glaze issued an unfavorable decision denying coverage on January 18, 2019 for ALJ Appeal No. 1-8071086400 that is the subject of this litigation. (Glaze Unfavorable Decision, at A.R. 2588-2598.)

17. Judge Glaze's decision covers Mrs. Piekanski's TTFT claims for TTFT coverage for the months of December 2017 – February 2018. (Glaze Unfavorable Decision, at A.R. 2594.)

18. Mrs. Piekanski raised the issue of Medicare coverage for her TTFT device by appealing the Qualified Independent Contractor's negative reconsideration decision in this case ("[t]his case is properly before the Office of Medicare Hearings and Appeals...pursuant to a timely request for hearing...following an unfavorable reconsideration..."). (Glaze Unfavorable Decision, at A.R. 2594.)

19. At issue in ALJ Glaze's unfavorable decision was whether TTFT was a Medicare covered benefit for Mrs. Piekanski ("[t]he issue is whether payment may be made for the...tumor treatment field therapy (E0766) provided to the Beneficiary..."). (Glaze Unfavorable Decision, at A.R. 2594.)

20. Judge Glaze found that TTFT was not a covered Medicare benefit for Mrs. Piekanski ("Medicare does not cover the tumor treatment field therapy (E0766) at issue."). (Glaze Unfavorable Decision, at A.R. 2598.)

21. Judge Glaze found that TTFT was not "reasonable and necessary" for Mrs. Piekanski ("... Medicare considers tumor treatment field therapy to not be reasonable and necessary ..."). (Glaze Unfavorable Decision, at A.R. 2598.)

22. Judge Gulin’s prior favorable determination on the same issue was provided to Judge Glaze prior to the hearing in this case. (*See Exhibit B* (“Glaze Prehearing Brief”), at A.R. 3175-3195.)

23. Mrs. Piekanski was represented by attorney Bridget Noonan at the Judge Ryan Glaze hearing held on August 7, 2019. (*See Exhibit D* (“Glaze Favorable Decision”), at A.R. 2491.)

24. Judge Ryan Glaze issued a favorable decision finding coverage for Mrs. Piekanski’s TTFT on September 13, 2019 for ALJ Appeal No. 1-8637781229. (Glaze Favorable Decision, at A.R. 2486-2495.)

25. Judge Glaze’s decision covers Mrs. Piekanski’s TTFT claims for TTFT coverage for the months of June – August 2018. (Glaze Favorable Decision, at A.R. 2491.)

26. ALJ Glaze noted that Mrs. Piekanski “seeks Medicare Part B coverage for TTFT...”. (Glaze Favorable Decision, A.R. at 2492.)

27. Mrs. Piekanski raised the issue of Medicare coverage for her TTFT device by appealing the Qualified Independent Contractor’s negative reconsideration decision in this case (“...coverage was denied on reconsideration. The Office of Medicare Hearings and Appeals (OMHA) subsequently received a request for an Administrative Law Judge (ALJ) hearing...”). (Glaze Favorable Decision, at A.R. 2491.)

28. At issue in ALJ Glaze's favorable decision was whether TTFT was a Medicare covered benefit for Mrs. Piekanski (the issue is "whether Medicare Part B covers the...TTFT (E0766) provided to the beneficiary..."). (Glaze Favorable Decision, at A.R. 2491.)

29. Judge Glaze found that TTFT was a covered Medicare benefit for Mrs. Piekanski ("Medicare Part B covers the Optune™ TTFT (E0766) provided to [Mrs. Piekanski]..."). (Glaze Favorable Decision, at A.R. 2495.)

30. Judge Glaze found that TTFT was "reasonable and necessary" for Mrs. Piekanski ("...the record before me clearly establishes that the device is medically reasonable and necessary to treat [Mrs. Piekanski's] condition."). (Glaze Favorable Decision, at A.R. 2495.)

31. The Secretary did not appeal this decision. (Fidanza Declaration ¶ 9.)

32. Mrs. Piekanski was represented by attorney Debra Parrish at the Judge Jenifer Soulikias hearing held on May 30, 2019. (See **Exhibit E** ("Soulikias Decision"), at A.R. 2476.)

33. On June 4, 2019, Judge Soulikias issued a favorable decision for ALJ Appeal No. 1-8415573880. (Soulikias Decision, at A.R. 2471-2485.)

34. ALJ Soulikias' June 4, 2019 decision covers Mrs. Piekanski's claims for TTFT coverage for the months of September - November 2018. (Soulikias Decision, at A.R. 2475.)

35. Judge Soulikias noted that Mrs. Piekanski was “challenging the denial of coverage for an electrical stimulation device...”. (Soulikias Decision, at A.R. 2481.)

36. Mrs. Piekanski raised the issue of Medicare coverage for her TTFT device by appealing the Qualified Independent Contractor’s negative reconsideration decision in this case (the “Qualified Independent Contractor (QIC)...issued an unfavorable decision” and Mrs. Piekanski subsequently “filed a request for hearing before an ALJ...”). (Soulikias Decision, at A.R. 2475.)

37. At issue in ALJ Soulikias’ decision was whether TTFT was a Medicare covered benefit for Mrs. Piekanski (issue is “whether Beneficiary established the requirements for Medicare coverage.”). (Soulikias Decision, at A.R. 2481.)

38. ALJ Soulikias found that TTFT was a covered Medicare benefit for Mrs. Piekanski (“[Mrs. Piekanski] established by a preponderance of the evidence that the electrical stimulation device (code E0766) for TTFT at issue...meets the requirements for Medicare coverage.”). (Soulikias Decision, at A.R. 2483.)

39. ALJ Soulikias found that TTFT was “medically reasonable and necessary” for Mrs. Piekanski (“[Mrs. Piekanski] established by a preponderance of the evidence that the electrical stimulation device (code E0766) for TTFT at

issue is medically reasonable and necessary...”). (Soulikias Decision, at A.R. 2483.)

40. The Secretary did not appeal this decision. (Fidanza Declaration ¶ 11.)

41. Mrs. Piekanski was represented by attorney Bridget Noonan at the Judge James Myles hearing held on January 24, 2020. (See **Exhibit F** (“Myles Decision”), at 1.)

42. On January 29, 2020, Judge Myles issued a favorable decision for ALJ Appeal No. 3-8925380171. (Exh. F to Fidanza Declaration.)

43. ALJ Myles’ January 29, 2020 decision covers Mrs. Piekanski’s claims for TTFT coverage for the months of March – May 2019. (Myles Decision, at 1.)

44. ALJ Myles noted that the Beneficiary was seeking Medicare coverage of TTFT, as “Appellant submitted a claim for E0766: Tumor Treatment Field Therapy...” and thereafter appealed denials stating that the device was not reasonable and necessary. (Myles Decision, at 1.)

45. Mrs. Piekanski raised the issue of Medicare coverage for her TTFT device by appealing the Qualified Independent Contractor’s negative reconsideration decision in this case. (Myles Decision, at 1.)

46. At issue in ALJ Myles' decision was whether TTFT was a Medicare covered benefit for Mrs. Piekanski ("whether the TTFT provided...to the Beneficiary met Medicare coverage criteria."). (Myles Decision, at 1.)

47. Judge Myles found that TTFT was a covered Medicare benefit for Mrs. Piekanski ("based on the evidence, the TTFT devices provided to the beneficiary during the DOS...meet the Medicare criteria for coverage..."). (Myles Decision, at 7.)

48. ALJ Myles found that TTFT was "medically reasonable and necessary" for Mrs. Piekanski ("based on the evidence, the TTFT devices provided to the beneficiary during the DOS were reasonable and necessary..."). (Myles Decision, at 7.)

49. The Secretary did not appeal this decision. (Fidanza Declaration ¶ 13.)

50. After the Medicare Appeals Council failed to issue a ruling within 90 days as required upon her timely appeal of Judge Glaze's January 18, 2019 unfavorable decision, Mrs. Piekanski requested "escalation" pursuant to 42 C.F.R. § 405.1132. (See **Exhibits G-H**.)

51. Plaintiff attached the favorable determinations of coverage from Judges Gulin, Soulikias, and Glaze to her November 2019 escalation request. (**Exhibit G**, at A.R. 2460-2495.)

52. Each ALJ, for the purposes of his/her determination, characterized Mrs. Piekanski's GBM as either newly diagnosed or recurrent. Judge Gulin characterized it as newly diagnosed in his coverage decision (Gulin Decision, at A.R. 2470) ("newly formed glioblastoma like the Appellant's"); Judge Glaze initially characterized it as recurrent (Glaze Unfavorable Decision, at A.R. 2598) (Mrs. Piekanski has "recurrent glioblastoma"); Judge Glaze thereafter characterized it as newly diagnosed (Glaze Favorable Decision, at A.R. 2493) ("evidence sufficiently supports that the beneficiary's GBM can be considered newly-diagnosed"); Judge Soulikias characterized it as recurrent in her coverage decision (Soulikias Decision, at A.R. 2483) (Plaintiff's tumor was "confirmed to have progressed"); and Judge Myles characterized it as recurrent in his coverage decision (Myles Decision, at 5) (May 2018 MRI "revealed progression of the tumor").

Respectfully submitted,

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